M1350C
Series 50 XMO
$FSpO_2$ Measurement

INFORMATION FOR PRESCRIBERS

CLINICAL USE GUIDE

OPERATOR'S MANUAL

~~M1350-9101A~~

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~~Edition 1~~

PHILIPS

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Notice

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Manufactured by

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Caution

Federal law (USA) restricts this device to sale by or on the order of a ~~properly licensed practitioner~~ physician.

Printing History

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~~Clinical Equivalence~~

The Series 50 XMO (M1350C) uses Tyco Healthcare/Nellcor's technology for the $FSpO_2$ algorithm and sensor. ~~The Series 50 XMO parameter is clinically equivalent to Nellcor's OxiFirst (N-400) Fetal Oxygen Saturation monitoring System.~~ The results of the Nellcor clinical study ~~apply~~ also to the Series 50 XMO's $FSpO_2$ parameter. ~~There is no significant difference between the measurement in the N-400 and the XMO.~~

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Indications /Contraindications

Indications for Use, Contraindications, Warnings and Precautions

Intended Use/Indications for Use

The monitor ~~is~~ continuously monitor intrapartum fetal oxygen saturation ($FSpO_2$). Use of the ~~measurement is~~ indicated **as an adjunct** to fetal heart rate monitoring in the presence of a non reassuring fetal heart ~~trace~~ pattern. It should only be used after ~~maternal~~ membranes have ruptured and on a singleton fetus in vertex presentation with a gestational age greater than or equal to 36 weeks.

Contraindications

Use of the measurement is contraindicated in patients with the following conditions

- Documented or suspected placenta previa
- Ominous FHR pattern requiring immediate intervention
- Need for immediate delivery (unrelated to FHR pattern), such as active uterine bleeding.

Safety Definitions

Warning: Alerts the reader to hazards or potential serious outcomes to patient or users that may result from misuse of the $FSpO_2$ parameter.

Caution: Alerts the reader to exercise special care necessary for the safe and effective use of the measurement. May also alert the reader to adverse effects on the monitor of use or misuse and the care necessary to avoid such effects.

~~Precautions: Indicates that a grouping of two or more cautions follows.~~

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Warnings and Precautions

Warnings

- The measurement is intended **as an adjunct** to fetal heart rate monitoring in fetuses with a nonreassuring heart rate pattern. It must be used in conjunction with clinical signs and symptoms.
- The monitor should not be used while using an Electrosurgical Unit (ESU). Remove the fetal oxygen sensor from the mother and fetus before using an ESU. An improperly grounded ESU can cause surface skin burns on the fetus if both the monitor and an ESU are used together.
- The monitor should not be used in the presence of flammable anesthetics. Such use may constitute a fire or explosion hazard.
- The monitor should not be used to monitor patients during water births, in whirlpool or submersion water baths, during showers, or in any other situation where mother is immersed in water. Doing so may result in electrical shock hazard.
- The measurement should not be used in women with active genital herpes or other infection precluding internal monitoring. Insertion of the fetal oxygen sensor in these women may result in transmission of pathogens to the fetus.
- The measurement should not be used in women who are seropositive for human immunodeficiency virus (HIV). Insertion of the fetal oxygen sensor in these patients may result in fetal exposure to the virus.
- Intrauterine insertion of the fetal oxygen sensor in women who are seropositive for Hepatitis B and/or Hepatitis E antigens may result in fetal exposure to these antigens.

Precautions

Clinical Use Precautions

- Physicians and other licensed practitioners who use the measurement should have demonstrated expertise in determining fetal presentation and head position, and should be proficient in fetal scalp electrode and intrauterine pressure catheter placement.
- Do not attempt to insert the sensor if patient is dilated less than 2 cm or if amniotic membranes have not ruptured. Doing so may result in erroneous $FSpO_2$ measurements and/or patient injury.
- Do not attempt to rupture amniotic membranes with the sensor. Doing so may result in patient injury and/or sensor malfunction.

- Do not leave the fetal oxygen sensor in place during vacuum extraction, forceps delivery or cesarean delivery. Doing so may result in patient injury. Remove the fetal sensor before commencing any form of operative delivery.
- Do not reinsert a stylet into the sensor cable chamber once it has been completely removed during sensor placement. Doing so may result in maternal injury. Sensor adjustments can be accomplished without the stylet being inserted into the sensor.
- Suboptimal sensor placement, excessive vernix, fetal hair or motion artifact (due to uterine contractions or maternal position changes) may result in no $FSpO_2$ values being displayed, or erroneous $FSpO_2$ values.
- If the fetal heart rate slows during vaginal exam or sensor insertion, stop the procedure. Do not proceed with sensor placement as this can cause a reflex bradycardia stimulus. Wait for the fetal heart rate to return to the previous range before proceeding.
- The fetal oxygen sensor may be left in place during defibrillation but $FSpO_2$ readings may be inaccurate for a short time.
- Do not use the monitor or fetal oxygen sensor during MRI scanning. Strong magnetic fields may affect the device causing erroneous $FSpO_2$ measurements.

Technical Precautions

- Do not attempt to use any sensor other than sterile, single-use Nellcor® Fetal Oxygen Sensors (FS-14 Series) with the monitor. Use of any other Nellcor oximetry sensor or any sensor from another manufacturer may result in system malfunction, erroneous $FSpO_2$ readings, and/or patient injury.
- Do not use a damaged sensor. Doing so may result in patient injury, sensor malfunction, and/or erroneous $FSpO_2$ measurements.
- Never attempt to clean, reprocess or re sterilize fetal oxygen sensors. Doing so may result in sensor malfunction, erroneous $FSpO_2$ measurements, and/or infection or potential tissue injury to mother and/or fetus. Each fetal oxygen sensor is supplied as a sterile, single-use, disposable device.
- Do not attempt to remove the outside monitor cover. Doing so may result in electrical shock hazard. There are no user-serviceable parts inside.
- Replace fuses only with those of the same type and rating to protect against fire hazard.

- Do not immerse the sensor completely in liquid (the connector is not waterproof). Immersion of the sensor plug in liquid may result in sensor malfunction and/or erroneous $FSpO_2$ measurements.
- Do not use any accessory equipment with the monitor unless it is recommended in this manual, the Series 50 XMO *Instructions for Use* or other Philips literature.

2
Information For Prescribers

Introduction and Background

- System Overview
- System Components
- Device Description
- Theory and Principles of Operation

System Overview

The Series 50 XMO Fetal/Maternal monitor (the monitor) can continuously monitor intrapartum fetal oxygen saturation ($FSpO_2$). Use is indicated **as an adjunct** to fetal heart rate (FHR) monitoring in vertex presentation, singleton fetuses ≥ 36 weeks gestation with a nonreassuring FHR pattern as defined in the Sensor Placement Criteria located in this document.

The Series 50 XMO $FSpO_2$ measurement is fundamentally equivalent to the Nellcor OxiFirst™ Fetal Oxygen Saturation Monitoring System (N-400).

System Components

The Series 50 XMO $FSpO_2$ measurement comprises:

- Philips Series 50 XMO Fetal/Maternal monitor (M1350C)
- Philips M1365A Patient Module
- OxiFirst™ Fetal Oxygen Sensor, Series FS14

Device Description

The monitor's pulse oximetry system is used during labor and delivery to measure fetal oxygen saturation ($FSpO_2$).

The sensor is inserted transcervically into the mother's uterus and is positioned against the cheek or temple of the fetus. Two light emitting diodes (LEDs) located within the sensor shine light into fetal tissue and back-scattered light is received by an adjacent photodetector.

Hardware and software within the monitor process this signal to determine the oxygen saturation and pulse rate of the fetus and assess the quality of the optical signals. The values of saturation are displayed on the monitor's front panel (along with other indicators) and are communicated to external equipment via serial and/or analog ports.

A diagram of the measurement in context is shown below.

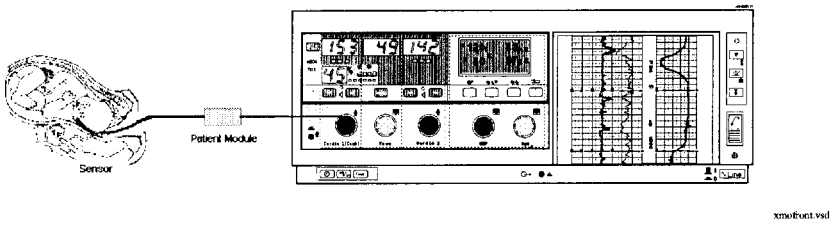

Figure 1: Series 50 XMO Monitoring $FSpO_2$

The fetal sensor is inserted into the mother's uterus following spontaneous or artificial rupture of amniotic membranes. The sensor rests against the fetal face during monitoring and it does not penetrate the fetal skin. It is supplied sterile, packaged in a pouch for single use only. The sensor body is molded around the optical components and is made from a soft plastic with no sharp or abrasive surfaces.

The monitor automatically calibrates itself each time it is powered on, at periodic intervals thereafter, and whenever a new sensor is connected. The pulse indicator on the oximeter front panel indicates the relative pulse amplitude of the photoplethysmogram.

Theory and Principles of Operation

The technology used in the monitor, like that of other pulse oximetry monitors, is based upon two basic principles. The first is that oxyhemoglobin (O_2Hb) and deoxyhemoglobin (HHb) differ in their ability to absorb light according to wavelength. The second is that the volume of arterial blood in tissue (and hence, the light absorption by that blood) changes during the pulsatile flow produced by each cardiac cycle.

Adverse Events

- Neonatal Deaths
- Adverse Events Observed in Maternal and Fetal/Neonatal Patients
- Potential Adverse Events
- Medical Device Reporting Reminder

Reports of any adverse events were collected from all mothers and babies enrolled in the Pilot (179) and Randomized Phases (1011) of the OxiFirst™ Fetal Oxygen Saturation Monitoring System trial (N=1190).

Neonatal Deaths

No neonatal deaths occurred within 24-hours of birth in the Pilot Study or the Randomized Controlled Clinical Trial. There were five neonatal deaths at later times following birth. Three (3) neonatal deaths were in the FHR + $FSpO_2$ group. The causes of death included two congenital cardiac anomalies and one cerebral infarction. Two (2) neonatal deaths occurred in the FHR-Alone group, both babies had congenital cardiac anomalies. There were no maternal deaths.

Adverse Events Observed in Maternal and Fetal/Neonatal Patients

Thirty-three percent (33%) of the maternal population experienced one or more adverse event(s) in the FHR + $FSpO_2$ group, versus 30% in the FHR-Alone group. The most frequently reported adverse events in the mothers were fever, mucus membrane disorder, and urinary retention. The category of "mucus membrane disorder" included the adverse events of amnionitis, chorionitis, endometritis and chorioamnionitis. The number of laboring patients placed on antibiotics during the study was similar in both groups, with 46% of those in the FHR + $FSpO_2$ group receiving antibiotics compared with 41% in the FHR-Alone group (NS). There were no statistically significant differences in the occurrence of any specific adverse event reported across treatment groups for either maternal or fetal/neonatal patients.

In the fetal/neonatal patients, one or more adverse event was reported in 70% of the FHR + $FSpO_2$ group and 64% in the FHR-Alone group. The most frequently reported adverse event in the neonatal population included ecchymosis, accidental injury, perinatal disorder, jaundice, and dyspnea. Included in the

category of "perinatal disorder" was temperature instability and symptoms of respiratory distress. The number of infants in the FHR-Alone group who experienced no adverse event was 180 (36%) compared with 152 (30%) in the FHR + $FSpO_2$ group (p = 0.029).

All serious adverse events in the FHR + $FSpO_2$ group are listed in Table 1 (Maternal) and Table 2 (Fetal/Neonatal) along with the corresponding information for the FHR-Alone group.

In the study, a serious adverse event was defined as an adverse event that required major medical or surgical treatment outside the realm of routine obstetrical/neonatal care, such as: excessive hemorrhage, uterine perforation, or other serious injury to mother, fetus, or neonate.

Table 1: Incidence of Maternal Serious Adverse Events

OxiFirst™ Fetal Oxygen Saturation Monitoring System Pilot Study and Randomized Controlled Trial		
Body System Adverse Event N (%)	FHR N=552	FHR + $FSpO_2$ N=638
Body as a Whole		
Fever	1 (0.2)	3 (0.5)
Cellulitis	1 (0.2)	1 (0.2)
Headache	1 (0.2)	1 (0.2)
Mucus membrane disorder	0	1 (0.2)
Cardiovascular System		
Thrombophlebitis	1 (0.2)	1 (0.2)
Metabolic/Nutritional		
Healing abnormal	0	2 (0.3)
Respiratory System		
Pneumonia	0	1 (0.2)
Urogential System		

OxiFirst™ Fetal Oxygen Saturation Monitoring System Pilot Study and Randomized Controlled Trial		
Endometrial disorder	6 (1.1)	5 (0.8)
Postpartum hemorrhage	3 (0.6)	3 (0.5)
Hemorrhage of pregnancy	0	1 (0.2)
Ruptured uterus	2 (0.4)	1 (0.2)

The incidence of maternal serious adverse events in the FHR + $FSpO_2$ group was 15 (2.4%) mothers with 92 (14.4%) of fetuses/neonates experiencing one or more serious adverse events. The most frequently reported maternal serious adverse event was endometrial disorder, postpartum hemorrhage, and fever (Table 1).

The most frequently reported fetal/neonatal serious adverse event was dyspnea, sepsis, hypoglycemia, and perinatal disorder (Table 2).

Table 2: Incidence of Neonatal Serious Adverse Events

OxiFirst™ Fetal Oxygen Saturation Monitoring System Pilot Study + Randomized Controlled Trial		
Body System Adverse event N (%)	**FHR N=552**	**FHR +$FSpO_2$ N=638**
Body as a Whole		
Sepsis	15 (2.7)	19 (3.0)
Perinatal disorder	5 (0.9)	9 (1.4)
Fever	1 (0.2)	3 (0.5)
Accidental injury	0	1 (0.2)
Withdrawal syndrome	0	1 (0.2)
Congenital anomaly	0	1 (0.2)
Cardiovascular System		
Heart malformation	1 (0.2)	3 (0.5)
Bradycardia	1 (0.2)	2 (0.3)
Cardiovascular disorder	3 (0.6)	2 (0.3)
Hemorrhage	1 (0.2)	1 (0.2)
Aortic stenosis	1 (0.2)	1 (0.2)
Tetralogy of Fallot	0	1 (0.2)
Pallor	2 (0.4)	1 (0.2)

OxiFirst™ Fetal Oxygen Saturation Monitoring System Pilot Study + Randomized Controlled Trial		
Digestive System		
Jaundice	0	1 (0.2)
Gastrointestinal Disorder	0	1 (0.2)
Hemic/Lymphatic		
Hypovolemia	2 (0.4)	3 (0.5)
Polycythemia	0	2 (0.3)
Thrombocytopenia	0	1 (0.2)
Anemia	2 (0.4)	1 (0.2)
Metabolic/Nutritional		
Hypoglycemia	9 (1.8)	8 (1.3)
Cyanosis	1 (0.2)	3 (0.5)
Bilirubinemia	2 (0.4)	2 (0.3)
Acidosis	2 (0.4)	1 (0.2)
Musculoskeletal - Myopathy	0	1 (0.2)
Nervous System		
Meningitis	0	2 (0.3)
Hypotonia	3 (0.5)	1 (0.2)
Facial paralysis	0	1 (0.2)
Respiratory System		
Dyspnea	21 (3.8)	26 (4.1)
Hyperventilation	0	6 (0.9)
Respiratory disorder	7 (1.3)	5 (0.8)
Pneumothorax	2 (0.4)	4 (0.6)
Apnea	3 (0.5)	1 (0.2)
Bronchitis	0	1 (0.2)
Hypoventilation	3 (0.5)	1 (0.2)
Pneumonia	3 (0.5)	1 (0.2)
Skin Skin Disorder	0	1 (0.2)

Potential Adverse Events

Possible risks or potential adverse events, not observed during the study, include maternal discomfort from sensor placement, umbilical cord damage, perforated uterus, and damage to the placenta.

Medical Vigilance Reporting Reminder

Medical device manufacturers and users are required by law and regulation to report serious injury and death.

Clinical Study

- Purpose of the Study
- Study Design
- Patients Studied
- Methods
- Results
- Device Performance
- Post Hoc Observations of Clinical Behavior Surrounding Periods of $FSpO_2 < 30\%$
- Individualization of Treatment

Purpose of the Study

The objectives of the study were:

- To assess whether the addition of the OxiFirst™ Fetal Oxygen Saturation Monitoring System to standard fetal heart rate (FHR) monitoring, within a defined treatment protocol, results in a clinically meaningful and statistically significant reduction of the rate of Cesarean deliveries performed for the indication of nonreassuring fetal status (NRFS).
- To assess whether using the OxiFirst™ System, as an adjunct to FHR monitoring permits the safe continuation of labor during periods of nonreassuring fetal status. Use of the system is intended to continue labor during periods of nonreassuring FHR when the $FSpO_2$ is $\geq 30\%$ between contractions. The use of the system is not intended to determine when to interrupt labor.
- To assess the safety of placement, presence and removal of the fetal oxygen sensor.

The above objectives focused on reducing Cesarean deliveries performed for the indication of nonreassuring fetal status, as a surrogate for the specificity of diagnosis for non-reassuring fetal status, without causing injury to mother or baby. The study was not designed to determine the sensitivity of the OxiFirst™ System at detecting fetal acidosis, or to examine other indications and modes of delivery such as assisted vaginal or Cesarean deliveries performed for reasons other than nonreassuring fetal status. In particular, there is no physiologic reason to believe that better intrapartum diagnosis of fetal oxygenation would have any

impact on Cesarean delivery for dystocia or other reasons unrelated to fetal oxygenation.

Study Design

A three phase multi-centre clinical trial was designed to test for the clinical utility and safety of $FSpO_2$ monitoring with the OxiFirst™ Fetal Oxygen Saturation Monitoring System. Phase 1 was a Baseline observational study, without the use of $FSpO_2$ monitoring or a clinical management protocol. Phase 2 was a Pilot Study to familiarize investigators with the randomization system, placement and use of the OxiFirst™ Fetal Oxygen Saturation Monitoring System, and the clinical management protocol. Phase 3 was the multi-center Randomized Controlled Trial (RCT). In Phase 3, eligible patients were randomized to Test or Control groups, monitored by $FSpO_2$ + FHR (Test group) or FHR-Alone (Control group), managed during labor according to a defined patient care protocol in both groups, and observed for maternal and fetal outcome.

The major maternal outcome measures were the rate of Cesarean deliveries associated with nonreassuring fetal status and maternal safety measures. The major fetal outcome measures were neonatal status at birth and events of the immediate postpartum period.

Patients Studied

The study population was laboring women with ruptured membranes with nonreassuring fetal heart rate patterns.

Methods

Patients who met the inclusion/exclusion criteria were randomized into either the Test or Control group of the trial. Control patients were managed with conventional electronic FHR monitoring (FHR-Alone) and Test patients were managed with conventional FHR monitoring and the OxiFirst™ System.

During labor, the fetal heart rate tracing was classified as outlined in Table 3.

Table 3: Fetal Heart Rate Classification

FHR Classification	FHR Criteria
I	**Reassuring Group:** Any FHR pattern that did not meet criteria for Groups II or III.
II	**Nonreassuring Group:** Any one of the following for > 15 minutes: 1. Persistent late decelerations (> 50% of contractions) 1. Sinusoidal pattern[a] 1. Variable decelerations with one or more of the following: A relative drop of ≥ 70 bpm or an absolute drop to ≤ 70 bpm for > 60 seconds[b] Persistent slow return to baseline Long term variability < 5 bpm[c] Tachycardia > 160 bpm 1. Recurrent prolonged decelerations (2 or more below 70 bpm for > 90 seconds) Any one of the following for > 60 minutes: 1. Tachycardia > 160 bpm with long term variability < 5 bpm 1. Persistent decreased variability (≤ 5 bpm for > 60 minutes) [3]
III	**Ominous Group:** Prolonged deceleration to < 70 bpm for > 7 minutes

a. Sinuosoidal pattern were defined as regular oscillations about the baseline, 5-15 bpm in magnitude, with 2 to 5 cycles per minute on an otherwise normal baseline with absent short-term variability.
b. Variable decelerations were to be timed from the beginning of the deceleration to the end of the deceleration (ie, >60 sec in duration)
c. Decreased variability not otherwise explained by the clinical situation (ie, narcotic administration)

Fetal heart rate classification: FHR tracings were characterized according to the values of the baseline heart rate, the presence or absence of variability and accelerations, and the presence or absence of decelerations. Typically, the Classification I trace was characterized by a baseline between 110 and 160 bpm, with long term variability between 5 and 25 bpm, and either no decelerations or only early decelerations.

Patients were managed according to a clinical management protocol that was guided by the FHR Classification alone in the Control group and a combination of the FHR Classification and oxygen saturation data in the Test group. The clinical management protocols for both study groups of the study are described in the following table.

Table 4: Clinical Management Protocol (Matrix)

FHR-Alone	**FHR PATTERN GROUP**	**FHR and Oximeter**	
		$FSpO_2$ Not Reassuring[a]	**$FSpO_2$ Reassuring[b]**
Continue labor unless otherwise indicated [3]	**Class I – Reassuring FHR**	Continue labor unless otherwise indicated [c]	Continue labor unless otherwise indicated [c]
Evaluate and manage nonreassuring FHR	**Class II - Nonreassuring FHR**	Evaluate and manage nonreassuring FHR	Continue labor unless otherwise indicated [c]
Deliver for fetal distress	**Class III - Ominous FHR**	Deliver for fetal distress	Deliver for fetal distress

a. $FSpO_2$ Not Reassuring = $FSpO_2$ remains < 30% between contractions, or no value available despite sensor adjustment.
b. $FSpO_2$ Reassuring = $FSpO_2$ returns to a value of ≥ 30% between contractions.
c. All corrective non-operative measures are allowed as in protocol text

Clinical management protocol for control and test groups of randomized controlled clinical trial phase of the study: The management procedure for patients in the control group is given by the column titled "FHR-Alone" and depends on the FHR classification (row). The management procedure for patients in the test group using the combination of FHR and oxygen saturation ($FSpO_2$) monitoring is given in the right hand two columns according to the intersection of the FHR tracing (row), and the $FSpO_2$ condition (column). See text for details on actions to be taken when the decision procedure calls for Evaluate and Manage Nonreassuring FHR or Deliver for Fetal Distress.

During the RCT, when the action called for in Table 4 was "Evaluate and manage nonreassuring FHR," the clinician was instructed to execute a series of escalating maneuvers intended to improve fetal oxygenation in an attempt to correct the condition(s) which triggered the abnormal state. The maneuvers included:

- Maternal repositioning to achieve uterine displacement
- Hydration
- Correct hypotension
- Tocolytic for hypertonic contractions
- Maternal oxygen
- Amnio-infusion
- Assessment and correction of oxytocin drug dose

In addition, if the fetus was being monitored with the OxiFirst™ System and no $FSpO_2$ value was being displayed, the clinician adjusted the sensor in an attempt to optimize placement.

If the protocol matrix following the corrective maneuvers still indicated "Evaluate and Manage Nonreassuring FHR", the clinician used the evaluation protocol described in Figure 2 to obtain additional information regarding fetal well-being.

Figure 2: Fetal Evaluation Protocol

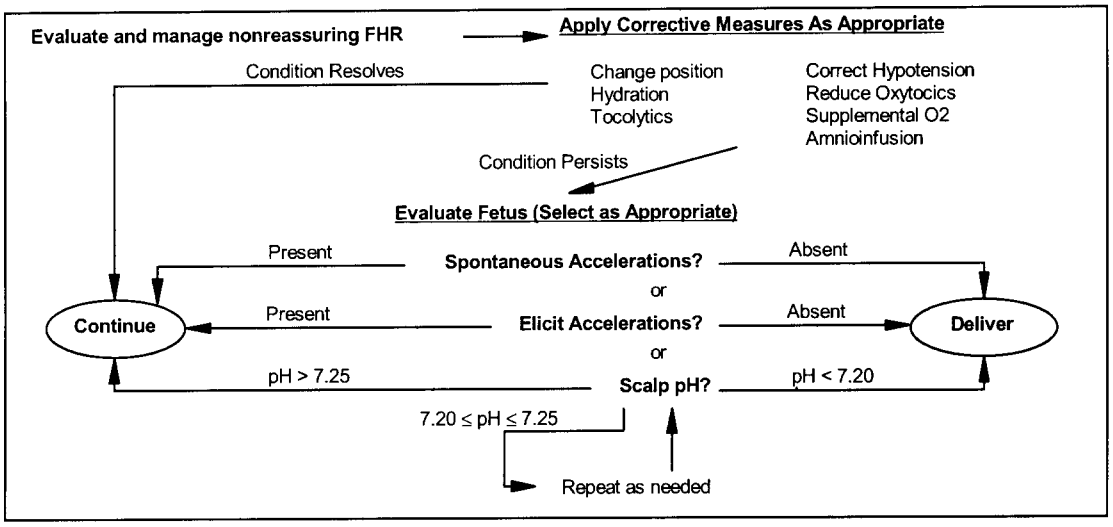

Figure 2. Fetal Evaluation Protocol. Protocol for evaluating the state of fetal well being.

Results

The principal effectiveness and safety results demonstrated by the RCT are:

- The study showed no change in overall Cesarean rates. Cesareans for NRFS were reduced by 50% in the group monitored with FHR+FSpO_2 while Cesareans for dystocia increased (for reasons not explained by the available data).
- The continuation of labor during periods of nonreassuring fetal heart rate patterns permitted by the use of OxiFirst™ FSpO_2 monitoring does not result in any adverse impact on the neonate.
- The placement, presence, and removal of the Fetal Oxygen Sensor does not alter the safety profile of labor and delivery when compared to the use of the FHR alone.

Compared with the Baseline phase, the Cesarean rate for all indications was significantly higher in both groups of the RCT (20% in the Baseline versus 26% in the FHR group and 29% in the FHR+$FSpO_2$ group). Cesarean deliveries for NRFS were also significantly higher in the FHR group of the RCT versus Baseline (5.3% Baseline; 10.2% FHR; 4.5%, FHR+$FSpO_2$).

The overall incidence of assisted vaginal delivery in the RCT was not different between groups (23% FHR and 24% FHR+$FSpO_2$) neither was the incidence of NRFS as the indication for AVD (11.3% FHR and 10.8% FHR+$FSpO_2$).

Device Performance

An $FSpO_2$ signal was obtained in 95% of the test subjects where sensor placement was attempted. When a sensor adjustment or replacement was made during a period of no $FSpO_2$ display, the signal was restored in 88% of cases. The median time between the adjustment and re-display was three (3) minutes.

In 39 cases (8%), a $FSpO_2$ sensor was not placed in women assigned to the FHR+$FSpO_2$ group. Reasons for non-placement of sensors are given in Table 5.

Table 5: Summary of reasons device placement not attempted

OxiFirst™ Fetal Oxygen Saturation Monitoring System Randomized Controlled Trial	
Reasons device placement not attempted [a]	**FHR+$FSpO_2$ Group N=508**
Imminent delivery	15
Decision to C/S made prior to placement	7
Patient withdrew	7
Not eligible (discovered after patient was enrolled)	4
Physician withdrew	3
Research nurse not available	2
Heart rate ominous	1
Equipment failure	1

a. More than one reason was reported in two patients

In the 469 patients in whom an attempt was made to place the sensor, placement was successful in 446 (95%), and unsuccessful in 23 (5%) (Table 6).

Table 6: Summary of reasons for unsuccessful sensor placement

OxiFirst™ Fetal Oxygen Saturation Monitoring System Pilot Study +Randomized Controlled Trial	
Reasons for unsuccessful sensor placement	**FHR+$FSpO_2$ Group N=508**
Difficult / other	10
Imminent delivery	5
Advanced Dilation	4
Fetal Bradycardia	1
High station / not eligible	1
Vernix	1
Decision to Cesarean delivery prior to sensor readings available	1

$FSpO_2$ values at a single point in time may not provide an exact measure of fetal arterial oxygen saturation. When the $FSpO_2$ value is observed over time, the system more accurately reflects the true oxygenation status of the fetus (-0.6 percentage difference between SaO_2 and SpO_2 when tested in animal models). See footnote[1] for more information.

Post Hoc Observations of Clinical Behaviour Surrounding Periods of $FSpO_2$ < 30%

In this analysis, the entire monitoring period was divided into sequential epochs; each defined as the time that the $FSpO_2$ value was either High (≥ 30%), Low (< 30%) or Absent (no signal displayed) between contractions. The start of the first

1. Nellcor Fetal Oxygen Saturation Monitoring (N-400): Technical Issues (Application Note 5990-0505EN), reprinted by Philips from Nellcor's Perinatal Reference Note 1

epoch was when the signal was initially obtained, reading High or Low. Subsequent epochs (High, Low or Absent) began when the $FSpO_2$ state between contractions changed. Results and observations are from the 223 fetuses with at least one period of Low $FSpO_2$.

Most fetuses had relatively few epochs of low $FSpO_2$. The typical number of Low $FSpO_2$ epochs was one or two per fetus. The typical (median) duration of Low $FSpO_2$ epochs was short at 5 minutes. The typical (median) duration of absent signal was also short at 8 minutes. In contrast, the typical (median) duration of high $FSpO_2$ epochs was longer at 21 minutes. Thus, most of the time, the $FSpO_2$ is above 30% (reassuring) with relatively short signal absences. The majority of the Low $FSpO_2$ epochs (69%) recovered to a High $FSpO_2$ state, 27% were ended by a loss of signal, and 3% were followed by delivery of the fetus.

FHR patterns were not coupled to $FSpO_2$ status. Class 1 Reassuring FHR patterns and the various types of Class 2 Nonreassuring FHR patterns were distributed across the Absent, High, and Low $FSpO_2$ epochs in roughly the same proportion as the number of Absent, High, and Low $FSpO_2$ epochs themselves. This indicates that the two measurements are independent. This is to be expected since FHR and $FSpO_2$ measure different aspects of fetal physiology.

During the second stage of labor there were a significant number of Low $FSpO_2$ epochs as well as an increased number of intermittent signal dropouts.

In fetuses exhibiting the presence of one or more epochs containing both Low $FSpO_2$ and nonreassuring FHR patterns in the same epoch, there was a higher incidence of delivery by Cesarean (34% vs. 27%) and AVD (36% vs. 20%). For Cesarean deliveries there was a higher incidence of delivery for NRFS (24% vs. 12%) and FIL/DYS
(29% vs. 14%). This suggests increased clinician concern for these fetuses.

Individualization of Treatment

Patients who would benefit from use of this device are those who exhibit the nonreassuring FHR tracings described in the management protocol. In these patients the pivotal study demonstrated that the continuation of labor is safe during periods of nonreassuring FHR when the $FSpO_2$ is $\geq 30\%$ between contractions. The system is not intended to determine when to interrupt labor.

How Supplied

The monitor is supplied boxed with an electrical cable, fetal patient module, accessories and supplies for other measurements for which the monitor is designed, the Series 50 XMO *Instructions for Use*, and this Guide containing *Information for Prescribers, Clinical Use Guide, and Operator's Manual.*

Sensors are supplied sterile, for single use only, in boxes of six each by Nellcor.